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The cultural specifity of research ethics—or why ethical debate in France is different

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In the search for a globally binding ethical minimal consensus in dealing with research on human beings the awareness of the cultural specificity of such questions will be of central importance. France provides a good example of such cultural specificities. Three basic structures of French discussion on research ethics can be enumerated: first the particular weight placed on therapeutic benefit, second a particular accentuation on freedom and voluntarism, and third its lesser attention to the aspect of ability to give consent. The weak emphasis on the ability to give consent is rooted as much in the traditionally paternalistically imbued physician-patient relationship as in the French legal system, in which the doctrine of consent is not given the fundamental position of importance found in the Anglo-Saxon countries. As an important Roman country, a different accentuation in the ethical discussion on research on humans can be recognised, a discussion in which for a long time the right of self determination was less of a criterion for decision than the teleology of medical action. It is precisely this aspect of latent cultural influence in ethical convictions which is of decisive importance for future discussion on research on humans.

For a globally binding ethical minimal consensus in dealing with research on humans the awareness of the cultural specificity of such questions will be of central importance. The French discussion on research on human beings is of particular interest for the very reason that it shows signs of several nationally specific characteristics. This paper wants to show these national specifities in their social and historical context.

THE FRENCH DISCUSSION ON RESEARCH ETHICS PRIOR TO THE RESEARCH LAW OF 1988

One important characteristic of the French discussion lies in the fact that experimentation on humans was for a long time morally and legally considered to be fundamentally reprehensible.[1] Prior to the research law of 1988, all non-therapeutic research was considered illegitimate, and this was true of the French code of medical ethics as well as in the administration of justice.In the seventies, this legal condemnation of every non-therapeutic experiment proved to be increasingly problematic.[2] It stood in particularly crass contradiction to the alteration of the French pharmaceutical code as passed in 1975. This law altered the procedures for approval of medications, making mandatory the testing of substances on healthy subjects in analogy to the European guidelines.[3] Consequently, this called for experiments which were punishable according to the hitherto extant laws. Therewith arose a paradoxical legal situation which could not protect the pharmacologist from civil or criminal sanctions in cases of injury related to performing tests of medications. Relevant legal proceedings never occurred, but this legal situation had the consequence that a portion of the French pharmaceutical industry moved outside of the country. Statistics verify that in the eighties, two-thirds of the pharmacological experiments of the phase I and phase II approval procedures for the French pharmaceutical industry were performed in England.[4]

Under this increasing economic pressure, a first draft of a law was elaborated in 1983 about which, however, no agreement could be reached. A decision was made to present the draft firstly to the newly founded National Consultative Ethics Committee for Health and Life Sciences for evaluation. This committee presented an official statement in 1984 on the ethics of research on humans wherein it emphasised the necessity of experimentation on humans and proposed legal regulation.[5] One year after this express plea for legal regulation of research on humans the French government presented a new legal draft which, to a large degree, included the proposals of the national consultative ethics committee. In spite of the widespread acceptance of this legal draft among pharmacologists and legal specialists this plan failed for purely political reasons. In view of the pending elections of 1986 no one dared to present the bill to the parliament. It was feared that public opinion had not been adequately prepared for it.

The national consultative ethics committee succeeded in engendering public discussion on the ethics of research, through which the desire for more transparency in dealing with research on humans was increased. This had in turn the consequence that public consciousness and acceptance of the inevitable necessity of the non-therapeutic experiment gradually increased. Up to that period physicians had explained little, but quietly performed human experimentations. The public relations work of the national consultative ethics committee made sure that patients were finally better informed.

The actual catalyst of the research law was the so-called Milhaud scandal which dealt with research on comatose patients performed in Amiens without any form of consent of the relatives.[6] Milhaud had caused the death of a patient in persistent vegetative state by performing a non-therapeutic experiment without having asked the consent of the relatives.[2] It was an experiment performed on a patient 29 years old, who had been for three years in a persistent vegetative state. Milhaud wanted to evaluate the effectiveness of intraosseous transfusion of blood for patients in hypovolamic shock. For this reason he withdrew one litre of blood from the patient and reinfused it two minutes later intraosseously, with lethal effect.

The Milhaud scandal had engendered such social pressure that a new law was henceforth moved forward in rapid steps, leading to its passage within the month of December 1988. This important law formulated legally binding regulations for the entire field of biomedical research for the first time.

Initially conceived only as a regulation guiding the testing of pharmaceuticals, the final Law on the Protection of Persons who Consent to Biomedical Research, (the "Huriet law") now pertained to every type of biomedical research—with the exception of research on embryos and brain dead people. With this law France had one of the most comprehensive research laws ever passed.[7]

THE FRENCH RESEARCH LAW

In its basic tenor this law lies close to recognised known international guidelines. It differentiates between research with and without "direct individual beneft" and also declares non-therapeutic human experiments to be legal for the first time in France. The innovative elements of this law have to do with its exposition on the subject of consent and its legal anchoring of ethics committees.

To turn first to the ethics committees. From the beginning of the eighties, local ethics committees had spontaneously formed without a legal basis in France taking over, in the main, the responsibility of acting as advisory consultants in cases involving problematic research proposals. The Huriet law creates a legal basis for these committees. This law requires that all committees (consultative committees for the protection of persons consenting to biomedical research) include four biomedical scientists, a practising physician, two pharmacologists, a representative of the nursing professions, an ethicist, a representative of patients, a psychologist, and an attorney. Until the amendment of 1994, voluntary committee members were randomly drawn from a list; and as of 1994, every prefect of the French regions has been given the duty of selecting the members from lists proposing three names for each position. Altogether, about 60 such regional committees exist in France.

The second innovation has to do with its paragraphs on informed consent. The fact that this law makes written informed consent a prerequisite to research seems to be nothing unusual, unless one remembers that the duty to inform, at least according to French professional law, had formerly not been as binding as in some other countries. In the French legal system, the rights of physical freedom from injury and of the inviolability of the human body enjoy central legal protection, which is much more strongly weighted than the individual right of self determination by the patient.[8] Decisive here is the "French" view that legally protected rights such as life and physical integrity are not only protected in their qualities as individual rights, but also on the basis of general interest (*ordre public*), as not only the individual, but also the community has an interest in the preservation of these rights.[9] From this basic perception, it follows that the individual cannot be granted the right of free disposal over his or her body. While according to the German criminal code, the consent of the affected person is regarded to be a decriminalising factor, the French criminal code does not recognise the so-called "consent of the victim" (*consentement de la victime*) as a justification for injury to physical integrity.[10] This does not mean that such consent is not of considerable importance, but it does not suffice as an independent justification, particularly in vindicating violations of physical integrity, as this requires, according to French legal teaching, a so-called "authorisation by the law" (*autorisation de la loi*). Only a higher level of legal permission can justify violations of bodily integrity, and medical activity is precisely one of the best examples of such an "authorisation by the law". French law thus allows, but at the same time regulates and protects, the profession of physician, transferring implicit permission to the medical profession for the execution of all acts belonging to the usual performance of the profession without punishment—to be sure, this applies only when all of the laws and regulations governing the medical profession are adhered to. Patient consent is an important dictate according to the formulation of the French ethical code (*Code de Déontologie Médicale*) of 1979. Consent is thus—at the latest beginning with the professional code of 1979—a necessary but not sufficient precondition for the legitimisation of an injury to physical integrity. But beyond consent, for legitimisation in the sense of an authorisation by the law, it is of particular importance that the physician adheres to the tenets of the medical art in a given case, commits no immoral act and, in the first place, acts for therapeutic reasons in order to cure the patient. From this it follows that, prior to the research law of 1988, all injuries to bodily integrity which were not "authorised" by the curing intention of the physician or by specific laws, were to be viewed as punishable bodily harm.[11] This is altered in the French research law by the stronger weighting of informed consent. The law requires a "free, informed and expressed consent" (*consentement libre, éclairé et exprès*), as a legitimating factor. In the case of minors and the mentally incompetent, the law requires that consent be obtained from the parents or legal guardian in therapeutic experiments. The consent of the family advisory council or of the court dealing with matters of guardianship is required only in instances of experiments involving high risk or in cases of non-therapeutic human experiments (art L 209–10).[7] This means, for example, that new antipsychotic medication would be permitted in France on people institutionalised for a mental illness who were not competent to consent.

The demand for a "free, informed and express consent" contained in the law has been experienced as a nuisance and damaging to the relationship of trust, particularly by paediatricians and oncologists. Also the most recent physicians' statements make it clear that many French physicians continue to hold fast to the inheritance of earlier centuries. An example is provided in an editorial by Raymond Villey, the former president of the French Medical Association, in which he states: "the dyadic relationship between the patient and his physician does not include the possibility that the patient consents to experimentation".[12] Instead of a partnership-like physician-patient relationship in which the physician must explain more and the patient must make more decisions for himself, many prefer the dyadic relationship purely based on trust between physician and patient. It is thus apparent that the physician-patient relationship in France remains strongly bound to the tendencies of traditional ethical principles.[13] In many Mediterranean countries the trustworthiness within the physician-patient-relationship is given greater importance than is the right to information.

RESEARCH ON VULNERABLE GROUPS

In reference to research on persons with impaired decision making capacity, the national ethics consultative ethics committee declared in 1984 that non-therapeutic research done on this group of persons was to be condemned in principle:

> "Experiments on prison inmates, the mentally incompetent and on patients who suffered from illnesses having nothing to do with the respective study are considered to be incompatible with ethical principles. Although it is true that patients who suffer from an illness other than that of interest in a particular study may sometimes be considered to be in the position of a healthy control subject, they are in fact involved in a relationship of dependency on the physician. For this reason, this group must be excluded from research."[14]

The French national consultative ethics committee showed itself to be more restrictive than the Helsinki declaration on this point and it is remarkable that here prison inmates are placed on the same level as the unconscious and the incompetent in regard to ability to give consent. The research law of

1988 didn't follow this restrictive recommendation. It takes rather the position which has been taken by the Council of Europe in their Convention on Human Rights and Biomedicine. The French law defines three important vulnerable groups in all:

1. Persons deprived of their freedom by a judicial or administrative decision;

2. Minors, adults under guardianship, persons in medical or social establishments and patients in emergency situations, and

3. Pregnant or nursing women.

The most restrictive regulations are in regard to the groups of persons deprived of their liberty by a judicial or administrative decision, in particular, to prisoners. The law allows no research without direct benefit to this group and this without exception (art L 209–5). There are also strict criteria governing therapeutic trials in regard to persons deprived of their liberty. The legitimacy of therapeutic research is, in such cases, bound explicitly to a "greater benefit" (*bénéfice majeur*). In this manner the danger of an improper influencing of prison inmates is prevented.

From this rule it is apparent that in the French evaluation, the factor of free will plays a central role, indeed, a much more decisive one than the ability to give consent or competence. Thus it follows that the strictest ruling would not be for the incompetent, but for the group of "those most easily manipulated". That the question of competency had not played the central role for the governing body is demonstrated in the fact alone that the law includes no separate section on groups of incompetent persons. Instead, article 6 unites the following groups: "minors, adults under guardianship, persons in medical or social establishments and patients in emergency situations". Included in the group of persons in medical or social establishments are not only the occupants of homes for the elderly or even asylum applicant homes, but, indeed, every hospital patient. Non-therapeutic studies on this group of persons are permissible, as long as they do not represent a serious foreseeable risk to the experimental subject, promise to be of use to the group of persons to which the experimental subject belongs and cannot be achieved in any other way.

These combined groups of persons differ considerably in respect to their ability to give consent. One need only think of the group of adults under guardianship as compared to the persons in medical or social institutions. Thus, in this instance as well, the question of competency is not the most important factor guiding the decision, but the question of independence. What these diverse groups have in common is precisely the question of particular dependency and their vulnerability to external influence and manipulation. According to this law the vulnerability of a group of persons is thus essentially joined to the level of dependency. Only in this way can it be understood that adults under guardianship are put together with normal hospital patients in a single group. The underlying thought in the case of hospital patients is that their dependency on the treatment could impair their ability to make a free decision, for example, to go against the views of their physician who wants to conduct research.

While the regulations in regard to prison inmates have turned out to be particularly restrictive, the remarks on research on persons with impaired decision making capacity seem extremely permissive. Even if one takes into consideration that beyond these requirements consent by a relative or third party must be obtained, the term "no major foreseeable risk" (*aucun risque sérieux prévisible*) remains and this is clearly something other than only a minimal risk. In this manner the law in the end allows types of research which are not permitted in other European countries and which are also not permitted by the European Human Rights Convention on Biomedicine.[15] This formulation in the law differs not only from the formulation of the national consultative ethics committee in its statement of 1984, but also from the proposal of the Conseil d'Etat in its report of 1988, both of which use the term "minimal risk", which should be the only kind of risk permitted for all human beings. Taken together one may suspect that the difference in the legal text may rather be due to an editorial imprecision than a conscious liberalisation, as the term "minimal risk" does not appear in the entire legal text and the term "no major foreseeable risk" (*aucun risque prévisible sérieux*) is used even in articles dealing with healthy subjects (art L 209–14). None the less the regulations governing research on persons with impaired decision making capacity must be viewed as extremely permissive. This also holds true for other areas, including research on so-called "emergency patients" (*malades en situation d'urgence*) which mostly pertains to unconscious patients who must be treated immediately. In these emergency situations the law allows for the possibility of clinical studies even when only consent by a relative or third party can be obtained, although with the requirements that these studies have been systematically planned and previously reviewed by a consultative ethics committee, as the law prescribes (art L 209–9). This regulation was subsequently a subject of clear criticism so that in the revision of 1994 this possibility is limited to experiments with therapeutic benefit.

It is surprising that the remarks on the persons with impaired decision making capacity are extremely brief, while precisely the problem field of non-therapeutic research is particularly well regulated. An entire independent part of the code (five sections in all) is devoted to "research without direct therapeutic benefit" (*recherche sans finalité thérapeutique directe*). French law places very high requirements on those performing non-therapeutic experiments on humans. For example, the law precludes any form of payment to the subject. Only a compensation of a maximum of 20 000 French francs (approximately US$2500) per year and subject is allowable, at the same time a central subject registry is established to ensure systematic control of the frequency of participation. Furthermore, any type of non-therapeutic study is forbidden on non-health insured subjects and financial insurance of the experimental subjects must be guaranteed by a special liability and a liability insurance duty of the person responsible for the experiment. In this way French law provides for special protection for healthy volunteers while the protection of persons with impaired decision making capacity seems rather questionable.

The fact that this law declares human experiments on persons with impaired decision making capacity to be legal even in the absence of explicit consent can be explained largely in terms of the weak doctrine of consent in the French legal system and the thinking of French physicians. Because the right of self determination is not fundamental in France as it is in Anglo-Saxon countries, it is possible for experiments to be legitimised without consent. If the remarks on the protection of healthy subjects are, in contrast, differentiated and restrictive, this is to be explained by the fact that, in the consciousness of French physicians, lawyers, and politicians, it is less the consent of the patient that constitutes the legality of medical activity, but rather that the legitimisation is extrapolated from the teleology of medical activity itself. The central position of therapeutic outcome—in the French legal system as well as in the thinking of French physicians—makes it understandable that one can find very many debates and remarks on the problem of non-therapeutic research in the discussion in France. In the course of this discussion the protection of the subject is particularly accentuated, whereas the discussion on so-called persons with impaired decision making capacity has played only a subordinate role in the debate in France.

CONCLUSION

From 1945 until the late sixties we could find an almost uniformly negative judgment of human experiments on the part

of physicians and lawyers in France. The seventies are to be viewed as a phase of transition, during which the ethical discussion of research on human beings went through clear changes in France. Research on humans became increasingly recognised as an unavoidable necessity and the debate on the subject lost its dogmatic character. In place of a debate on the fundamental legitimacy of research on humans, questions of specific criteria for the performance of research became increasingly important; these finally culminated in the passage of a comprehensive independent research law in the year 1988. Some basic elements of the French discussion on research on humans can be singled out. One basic component is the particular weight placed on therapeutic benefit. This tradition makes it understandable that the most important point of controversy in the French discussion was on research on healthy subjects and not—as in Germany—research on patients with impaired decision making capacity. Because of this the French discussion revolved more intensely around the problem of non-therapeutic research than around the aspect of the lack of ability to consent. This is reflected in the French research law in that the protection of subjects is particularly accentuated and that the regulations concerning on the problem area of persons with impaired decision making capacity are rather rudimentary and offer no special level of protection for this group of persons.

A further basic structure feature of the French discussion on research on humans, which retained its importance even after the transitional phase of the seventies, is its particular accentuation on freedom and voluntarism. Just as the physicians insisted on their freedom to make medical decisions in their proclamation of "*médecine libérale*", the aspect of freedom of action for the experimental subject played a central role in the discussion of experiments on humans both before and after the seventies. This principle of freedom of decision and action of the experimental subject has clearly left its mark in the French research law, especially in that the most comprehensive protective regulations appear in regard to those persons who are in dependent situations and for whom liberty in providing consent could be questionable. This holds true for, for example, prison inmates, but also for persons without health insurance who are considered, in France, to be particularly needy.

The third and related basic component of the French discussion consists in its lesser attention to the matter of ability to give consent, even though for the first time the new law makes prior consent a prerequisite for any form of research. The weak emphasis on the ability to give consent is rooted as much in the traditionally paternalistically imbued physician-patient relationship as in the French legal system, in which the doctrine of consent is not given the fundamental position of importance found in the Anglo-Saxon countries, and to a lesser degree in Germany as well.

The situation in France thus represents an example of how an ethical discussion about research on human beings may appear which does not revolve only around consent and its alternative forms. As an important European country, a different accentuation in the ethical discussion on research on humans can be recognised, a discussion in which for a long time the right of self determination was less of a criterion for decision making than the teleology of medical action. It is just this aspect of latent cultural influence in ethical convictions which is of decisive importance for future discussions on research on human subjects. Thus, the French approach could be an instructive one, because it makes clear that for a good clinical practice of research the principle of self determination should be respected, but this has to be balanced with the principle of beneficence, and this is especially true for research ethics.

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